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EXAMINER	
FLOOD, MICHELE C	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/083,413	DOMB ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12,14-26 and 38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12,14-26 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In response to the receipt and entry of the Appeal Brief filed on June 27, 2005, the final Office action dated January 24, 2005 is hereby vacated because Applicant's arguments with regard to the teachings of Tapolsky et al. (U. S. Patent No. 6,159,498) have been found persuasive; and the Office action herein shall take its stead.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-12, 14-26, and 38 are under examination.

Response to Arguments

Applicant's arguments filed on June 27, 2205 have been fully considered but they are not fully persuasive for the reasons set forth in the previous Office action and for the reasons set forth below.

Claim Rejections - 35 USC § 112

Claims 1-4, 6-12, 14-26 and 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Insertion of the limitation "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount" in Claims 1 and 38 is still deemed new matter.

Applicant argues that the examiner has not provided an explanation of why the claims lack written description. Applicant further argues, "The specification therefore clearly defines a homeopathic amount of an agent which is less than the amount normally required to produce a desired pharmacological effect." In an attempt to assert that the aforementioned limitation is not new matter, Applicant directs the Office to page 35, example 8 to indicate that the newly inserted limitation is not new matter. However, Applicant's apparent argument is neither persuasive nor commensurate in scope to the limitations of the instantly claimed invention because nowhere in the present specification does Applicant expressly describe or define a homeopathic amount of an agent as less than a therapeutically effective amount by either expressed definition or by example. For instance, while Applicant appropriately argues that the specification as originally filed "*defines* homeopathy as a therapeutic approach based on the concept that disease conditions should be cured by administering drugs which, in healthy people, induce a symptom similar to that manifested by the disease one intends to treat (page 35, lines 16-19). Also typical of homeopathic treatments is that extremely low, sometimes infinitesimal (spelling in original application was incorrect), doses of the homeopathic remedy must be given in order to induce the desired therapeutic effect, whereas high doses of the same drug would actually cause the symptom picture of the disease one is seeking to cure (page 35, lines 19-23)", the Office notes that nowhere in the specification as originally filed does Applicant direct the instantly claimed invention to a composition wherein the "agent is present in a homeopathic amount, which is less than a therapeutically effect amount". Defining a "homeopathic amount" of an agent as

an amount which is less than a therapeutically effect amount is different from defining a homeopathic amount of an agent which is less than the amount normally required to produce a pharmacological effect or to "induce a symptom picture similar to that manifested by the disease one intends to treat" (or in other words, to induce symptoms of illness when administered in therapeutic amounts to healthy people), especially in view of Applicant's contention that the basis of homeopathy as a therapeutic approach for treating disease conditions is based on the concept that doses of a homeopathic remedy or agent must be given to in order to induce a therapeutic effect. Furthermore, in view of Applicant's arguments, it would appear that Applicant directs the instantly claimed invention to a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a bioactive amount of at least one herbal active agent or an agent present in a homeopathic amount, where the agent is present in a non-therapeutic amount. As argued it would appear that Applicant is asserting that a homeopathic amount has no therapeutic value or effectiveness as a therapeutic agent. Applicant cannot have it both ways. The instantly claimed composition should either have a bioactive amount of an agent or a homeopathic amount of an agent, wherein the agent is present in either in a therapeutic amount (or, in other words, a bioactive amount) or a homeopathic amount.

The specification as originally filed provides only for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a therapeutically amount of at least one herbal or homeopathic active agent, as set forth in the abstract of the specification. Moreover, it is clear from the specification that

Applicant intended to **include and not to exclude therapeutic amounts of bioactive herbals and homeopathic agents** in the making of the instantly claimed composition, as disclosed by Applicant in [0027] through [0036] and [0074], [0094], [0114], [0125], and [0135] through [0145] of Patent Application Publication No. US 2003/0003140 A1. Thus, the original concept of the invention has been narrowed to encompass compositions comprising an agent, wherein the agent is present in a homeopathic amount which is less than a therapeutically effect amount without any support in the as-filed specification. The insertion of the limitations is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure nor are there specific examples of the newly limited genus which would show possession of the concept of " wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of the above mentioned claim-limitation is considered to be the insertion of new matter for the above reasons.

As the above mentioned claim-imitation could not be found in the present specification, the recitation of the claim limitation is deemed new matter; and, therefore it must be omitted from the claim language, unless Applicant can particularly point to the specification for literal support.

Claims 1-4, 6-12, 14-26 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a (a) bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides and combinations thereof, wherein the agents are present in a therapeutically amount; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa, does not reasonably provide enablement for the instantly claimed composition as set forth in Claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims, as broadly claimed by Applicant.

The claims are directed to a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a (a) bioactive amount of at least one herbal active agent selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a

therapeutically amount; and (b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

While the specification has reasonably demonstrated a method of making and using a solid, self-bioadhesive composition for topical application that adheres to mucosal tissue comprising a therapeutically effective amount of a bioactive amount of herbal ingredients and/or bioactive agents and use thereof for the treatment of mucosal disorders, the specification is not enabled for the claim-designated composition comprising either a bioactive amount of at least one herbal active agent selected from the or an agent, as recited in the Markush groups of Claim 1, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount. The specification is non-enabling for the claim designated composition as the specification does not provide guidance as to how to identify any and all ingredients used in the making of an composition comprising a bioactive amount of at least one

herbal active agent, wherein the agent is present in a homeopathic amount and wherein in a homeopathic amount is defined as "less than a therapeutically effective amount", or how to determine such amounts as defined therein, and how to determine the effective therapeutic amounts of a homeopathic agent for use in the making of the claim-designated composition "which is less than a therapeutically effective amount". While the specification has reasonably demonstrated a composition comprising a therapeutically effective amount of an herbal bioactive agent present in a bioactive amount, other than the mere description for the general preparation of a homeopathic medicine for the treatment of a bacterial infections in [0141] to [0142], the specification does not adequately describe the source of the ingredients, the amounts of the ingredients or the therapeutically effective amounts of the ingredients to result the effect for incorporating a bioactive amount of at least one herbal active agent or any other agent, wherein the agent is present in a homeopathic amount which is less than a therapeutically effective amount to provide for the making and/or use thereof or the claim-designated composition.

At the time the invention was filed, the state of the art did not fully support the incorporation of homeopathic agents or homeopathic amounts of bioactive agents into the making of pharmaceutical compositions that were intended for the purpose of administration to subjects, particularly humans, to provide a therapeutic result in the treatment of disease conditions. *See* the 1999 quackwatch.com website reference entitled "Homeopathy: The Ultimate Fake" by Dr. Stephan Barrett. Even by Applicant's own admission, it would at least appear that the determination for the administration of a

therapeutically effective amount of a homeopathic agent is at best a matter of trial and error to provide effective means for treating mucosal disorders suffered by humans, as set forth in the disclosure at [0137]. Hence, it is highly unlikely that the skilled artisan at the time the invention was made would be able to make and/or use the claim-designated composition comprising a bioactive amount of any and all herbal active agents or any and all of the other instantly claimed ingredients, "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount". Moreover, the Office notes that with the filing of the Appeal Brief, Applicant has readily submitted "Exhibit B" (entitled "Questions and Answers About Homeopathy") that teaches, "Various explanations have been proposed as to how homeopathy might work. However, none of these explanations have been scientifically verified", on page 1, last two lines. On page 15 of "Exhibit B", under "8. What has scientific research found out about whether homeopathy works" also teaches, "The results of individual, controlled clinical trials of homeopathy have been contradictory. In some trials, homeopathy appeared to be no more helpful than a placebo; In other studies, some benefits were greater than one would expect from a placebo [citations omitted]."

In order to enable the skilled artisan to practice the invention as claimed, Applicant would have to describe the amounts of each of the instantly claimed agents intended to provide the claim-designated composition comprising a bioactive amount of at least one herbal agent or an agent selected from the recited Markush group of Claim 1, wherein the agent is a present in a homeopathic amount which is less than a therapeutically amount to provide the making and/or use thereof the instantly claimed

invention. Given the insufficient guidance in the specification as to what ingredients or amounts of ingredients encompass a "homeopathic agent which is less than a therapeutically effective amount", and the effective amounts of a bioactive amount of the ingredients to provide a homeopathic amount which is less than a therapeutically effective amount, the lack of working examples, the lack of correlative working examples, and the state of the art at the time the specification was originally filed, the claims would require an undue amount of experimentation without a predictable degree of success on the part of the skilled artisan.

Accordingly, it would take undue experimentation without a reasonable expectation of success for the skilled artisan to identify any and all ingredients used in the making of an solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising a bioactive amount of at least one herbal active agent, wherein the agent is present in a homeopathic amount and wherein in a homeopathic amount is defined as "less than a therapeutically effective amount", or how to determine such amounts as defined therein, and how to determine the effective therapeutic amounts of a homeopathic agent for use in the making of the claim-designated composition "which is less than a therapeutically effective amount", as claimed by Applicant.

Claims 1-4, 6-12, 14-26 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered uncertain by the phrase "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount" because it is unclear as to what is the subject matter to which Applicant intends to direct the instantly claimed invention. For example, Applicant claims a composition comprising a bioactive amount of at least one herbal active agent; however, the aforementioned phrase recites the term "agent" and it is unclear as to whether the phrase is intended to define the "a bioactive amount of at least an herbal active agent" or "an agent selected from the group consisting of analgesics, anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides and combinations thereof". The lack of clarity renders the claim very vague, ambiguous and confusing, since a "bioactive amount of at least one herbal active agent" can not be further defined as a "homeopathic amount, which is less than a therapeutically effective amount".

Claim 1 is rendered vague and indefinite by the phrase "wherein the agent is present is a homeopathic amount, which is less than a therapeutically effective" because it is uncertain as to what Applicant what is the meaning of "less than a therapeutically effective amount". For example, what functional effect does a "less than therapeutically effective amount" provide?

Although not rising to the level of indefiniteness, there is an apparent omission of a word in Claim 1, line 7. Perhaps, Applicant intended to insert the word "drug" after the term "antimalarial". Appropriate correction is required.

Claim 6 recites the limitation "wherein the herbal active agent or homeopathic agent" in lines 1-2. There is a lack of insufficient antecedent basis for this limitation in the claim, that is [the . . . homeopathic agent].

Claims 14 and 18 are rendered by the phrase "a salt of Carnallite" because it is unclear as to the subject matter Applicant intends to direct the subject matter of the invention, since a thorough search of both patent and non-patent literature did not result in any disclosure or suggestion of "a salt of Carnallite".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

Claims 1, 4, 6-8 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Green (W).

Applicant claims a solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising (a) a bioactive amount of at least one herbal agent selected from the group consisting of herbs, herb extracts, tinctures, essential oils, an mixtures thereof or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically amount; and (b) a pharmaceutically

acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosal. Applicant further claims the composition of claim 1, wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasitic agent, and combinations thereof. Applicant further claims the composition of claim 1, wherein the herbal active agent or homeopathic agent is selected from a recited Markush group of claim-designated plants, including Echinacea and Calendula; wherein the herbal active agent is an essential oil selected from a recited Markush group, including lavender oil and tea-tree oil; and, wherein the composition of claim 1 further comprises an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

Applicant's main argument is directed to the idea that Green fails to anticipate the instantly claimed invention because the composition taught by Green is not a self-bioadhesive composition as instantly claimed by Applicant. In attempt to establish that the composition taught by Green is not a self-bioadhesive composition, Applicant points to particular passages in the Green' reference. However, Applicant's argument is not persuasive because while Applicant argues that Green instructs the reader to hold the poultice in place, Applicant also points out that Green instructs the reader on how to prevent the poultice from sticking. Applicant cannot have it both ways. Therefore, the

Office maintains that Green teaches the instantly claimed invention because on page 284 bridging page 285, under "Clay Poultice", Green teaches a method of making a clay poultice comprising bentonite clay, water and herbal tinctures comprising diluting a herbal tincture with about half as much water (2 parts tincture to 1 part water) to form a mixture and adding the mixture to bentonite clay to form a paste, wherein the proportions of clay to liquid is a tablespoon of clay to each tablespoon of liquid. Green further teaches adding a few drops of Lavender or Tea Tree essential oil (5 to 10 drops) to the composition and applying the composition in a thickness of at least ¼ inch. Green also teaches a bentonite clay poultice for the mouth, teeth and gums, wherein the method of making the solid, self-bioadhesive composition for topical application and adhesion to oral mucosal comprises adding water to bentonite-clay (a natural solid bioadhesive carrier) to form a malleable peanut butter consistency, rolling the clay into a cylindrical form, and mixing the clay with finely powdered Echinacea root or Goldenrood root with the clay powder before adding the water or an herbal tincture of Poke root (*Phytolacca Americana*).

Finally Applicant further argues that Green does not teach the instantly claimed invention because the self-adhesive composition taught by Green does not comprise an agent wherein the agent is present in a homeopathic amount. As set forth in the rejection made under 35 U.S.C. 112, second paragraph, the metes and bounds of Claim 1, as drafted, are rendered vague and indefinite by the simultaneous recitation of "a bioactive amount of at least one herbal active agent" and "wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective

amount". Thus, given the broadest interpretation of Claim 1, the claim as drafted can be read as composition comprising a bioactive amount of at least one herbal active agent, namely bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, such as the self-bioadhesive composition taught by Green **or** an **agent** (namely analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof), "wherein the **agent** (that is analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof) is present in a homeopathic amount".

The reference anticipates the claimed subject matter.

Claims 1-4, 6-11, 15-17, 22-24, 26 and 38 are rejected under 35 U.S.C. 102(b or e) as being anticipated by Gilis (A* or N).

Applicant's claimed invention of Claims 1, 4, 6-8 and 24 was set forth above. Applicant further claims the solid composition of claim 1, wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal for at least 30 minutes; and, wherein the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissue adherence of at least 1 hour. Applicant further claims the composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations. Applicant further

claims the composition of claim 1, further comprising a non-herbal active agent. Applicant further claims the composition of claim 15, wherein the agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacine, and etidocaine; and, wherein the non-herbal agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes. Applicant further claims the composition of claim 22, wherein said polyhydric polymer is selected from a recited Markush group.

Gilis teaches a solid, self-bioadhesive composition for topical application that adheres to oral mucosal comprising a pharmaceutically active agent, from 80% to 90% of pre-gelatinized starch (a polyhyric polymer starch derivative), from 1% to 10% of a hydrophilic matrix forming polymer (such as polyacrylic acid, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxyypproppyl methylcellulose, sodium carboxymethyl cellulose and polyvinyl alcohol - - see Column 2, lines 10-23), sodium stearyl fumurate, and glidant. In Column 2, line 39 to Column 3, line 44, Gilis teaches examples of pharmaceutically active agents that can be used in the making of the referenced composition, including the essential oils of lemon, cinnamon, clove, *etc*; and, non-herbal active agents, indlucing hydrocortisone, benzocaine, *etc*. In Column 4, lines 65-67, Gilis teaches that the residency time of the referenced composition is about 9 hours when applicant applied to the gingiva. Gilis further teaches the referenced solid, self-

bioadhesive composition as a flat, disc shaped tablet, in Column 3, lines 49-50; and about 6.55 mm in diameter and 1.88b mm thick. *See* Column 4, line 1 to Column 5, line 55.

Given the broadest interpretation of Claim 1, the claim as drafted can be read as composition comprising a bioactive amount of at least one herbal active agent, namely bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, such as the self-bioadhesive composition taught by Gilis **or** an **agent** (namely analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof), "wherein the **agent** (that is analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof) is present in a homeopathic amount".

The reference anticipates the claimed subject matter.

Claims 1, 4, 6, 15-17, 22-24, 26 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Kanios et al. (E*).

Applicant's claimed invention was set forth above.

Kanios teaches a solid, self-bioadhesive composition for topical application that adheres to oral mucosal comprising a bioactive herbal agent, a solvent for the active agent and a plasticizer, from about 20 to 50% of a bioadhesive carrier; and a cohesiveness increasing amount of clay. *See* patent Claims 1-22. In Column 9, line 59

to Column 10, line 46, Kanios teaches that the bioadhesive carrier used in the making of the composition include various polysaccharides, such as methycellulose, hydroxyethylcellulose, and polyacyrilic polymers. Additives, such as binders, stabilizers, preservatives, flavorings, pigments and lecithin are further incorporated into the composition. In Column 12, line 51 to Column 31, line 56, Kanios teaches bioactive pharmaceutical agents that can be used in the making of the referenced composition including menthol, gentian, acid salts of procaine and lidocaine, *etc.*, hydrocortisone, various herbal active agents, *etc.* Kanios further teaches that the composition has a surface are from about 0.2 to about 100 cm2 in Column 10, lines 57 to 59.
given the broadest interpretation of Claim 1, the claim as drafted can be read as composition may comprising a bioactive amount of at least one herbal active agent, namely bioactive herbs, herbal extracts, tinctures, essential oils and mixtures thereof, such as the self-bioadhesive composition taught by Kanios **or** an **agent** (namely analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof), "wherein the **agent** (that is analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof) is present in a homeopathic amount".

The reference anticipates the claimed subject matter.

Claims 1, 4, 7, 22, 23, 24 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronchi et al. (O).

Applicant's claimed invention was set forth above.

Ronchi teaches a solid, self-bioadhesive composition comprising from about 1 to 50% of a mucoadhesive polymer selected from the group consisting of polycarbophil, polyacrylic acid derivatives and the salts thereof, cellulose derivatives, carboxymethyl ethers and vinylcarboxylic acid derivatives; plant extracts and essential plant oils, such as peppermint oil and pumilius pine oil. *See* claims.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-11, 15-17, 19, 22-24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilis (A* or N) in view of Iyer et al. (C*) and Friedman et al. (B*) with evidence provided by Lawless (V).

The teachings of Gilis are set forth above. Gilis teaches the claimed invention except for wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of and at least one of myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene, and wherein said monoterpenes with three unsaturations is of citrus oil selected from the group consisting of lemon, pomelo and citron. However, it would have been obvious to one of ordinary skill in the art at the time the invention was mad to add the instantly claimed ingredients having the claim-designated biochemical

properties to the composition taught by Gilis to provide the claimed invention because Iyer teaches antimicrobial compositions which can be used in the making or oral compositions and Friedman teaches antifungal compositions which can be used in the making of oral compositions. Firstly, Iyer teaches antimicrobial compositions comprising at least two antimicrobial agents, agent A and agent B, which exhibit reduce MIC values relative to the MIC for the agents making up the combination measured alone. For example, in Column 3, lines 11-26, Iyer teaches that agent A and agent B are selected from the group consisting of berberine, cedarwood oil, chloramphenicol, citral, citronella oil, cocamidopropyl dimethylglycine, *Glycyrrhiza glabra* extract, hinokitol, juicy fruit basil oil, juniper berries oil, lemon basil oil, lemon oil, and *Rosmarinus officinalis* oil. The compositions taught by Iyer are useful as therapeutic agents such as in oral hygiene products. Secondly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman further teaches that the herbal extracts are in the form of a tincture of botanical

materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients having the instantly claimed biochemical properties to the composition taught by Gilis to provide the claimed invention because Iyer teaches that the antimicrobial compositions of his invention can be used in the making of therapeutic oral hygiene products for growth control of bacteria, such as *Actinomyces viscosus, Campylobacter rectus, Fusobacterium nucleatum, Porphyromonas gingivalis, Streptococcus mutans* and *Streptococcus mutans* (see Column 3, lines 28-38 and 47-51); and Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory activity in addition to its antifungal activity, can be used in the making of oral products, and can be used in the treatment of disease conditions such as *Herpes zoster* and *Herpes simplex* infections, dental ulcers, stomatitis, aphthous ulcers, and abscesses (see Column 4, lines 31-37; Column 8, lines 36-42; Column 9, lines 66-67 to Column 10, lines 1-4; and Column 10, lines 30-51). One of ordinary skill in the art at the time the invention was made would have been further motivated and one would have had a high expectation of success to add the antimicrobial compositions taught by Iyer to the bioadhesive composition taught by Gilis to provide the claimed invention because Iyer teaches in Table 14 that the combination of the essential oil of lemon (which

comprises 70% limonene, myrcene, pinenes and sabinene, as evidenced by the teaching of Lawless) in combination with an antimicrobial Agent B results in a significant decrease in the MIC value against various microorganisms which cause oral or periodontal disease. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference.

According, the claimed the invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-4, 6-12, 15-17, 19, 22-24, 26 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilis (A* or N) in view of Friedman et al. (b*) and Shuch et al. (D*).

The teachings of Gilis are set forth immediately above. Gilis teaches the claimed invention except for comprising herb tincture active agents selected from the recited Markush group of Claim 6, and further comprising a salt selected from the group consisting of $MgBr_2$, NaCl, KCL and mixtures thereof. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the composition taught by Gilis to provide the instantly claimed invention Friedman teaches antifungal compositions comprising botanical tinctures which can be used in the making of therapeutic oral compositions and Shuch teaches compositions comprising homeopathic salts and herbal botanicals which can be used in the making of therapeutic oral compositions. Firstly, Friedman teaches a combination of an herbal extract and an essential oil which exerts prolonged antifungal activity on mucosal membranes. The herbal extracts include material selected from the group consisting of Plantago, Hypericum, Echinacea, Baptisia, Calendula, Myrrh, Phytolocca, Salvia, Catechu black, Coneflower, Krameria, Tsuga, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis (beehive material), and Sage; and the essential oils are selected from cinnamon oil, cajeput oil, citronella oil, eucalyptus oil, fennel oil, geranium oil, lavender oil, lemon oil, spearmint oil, myrte oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, and tea-tree oil (see Column 1, lines 6-10; Column 2, lines 38-59; and claims). In Column 5, lines 9-39, Friedman

further teaches that the herbal extracts are in the form of a tincture of botanical materials. In Figures 1 and 2, Friedman shows that the referenced compositions have prolonged activity against *Aspergillus niger* and *Candida albicans*. In Column 4, lines 18-37, Friedman teaches that the compositions can be used to combat fungal infection of mucosal organs and the oral cavity. Secondly, Shuch teaches a biologically absorbable dental composition comprising Vitamin C to promote healing of the mouth from gum disease and to reduce plaque build-up on the teeth; and coenzyme A-10 (ubiquinone) to enhance gum health. Other active agents comprising the composition taught by Shuch include Vitamin E; herbal extracts, e.g., Propolis, Echinacea, grape seed extracts, cranberry extract, stevia, tangerine oil, and lemon oil; and homeopathic tissue salts comprising potassium chloride and sodium chloride. See Column 2, lines 40-67, Column 3, and Column 4, lines 1-42. The formulation may be in the form of a dental prophylaxis paste (see Column 6, lines 64-67; and Examples 9-13, especially Examples 12 and 13, which comprise homeopathic salts). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the bioactive active agents taught by Friedman and Shuch to the composition taught by Gilis to provide the instantly claimed composition because Friedman teaches that the compositions of his invention have strong antibacterial activity and anti-inflammatory action in addition to antifungal activity, which can be used in the making of oral products for use in the treatment of disease conditions such as Herpes zoster and Herpes simplex infections, dental ulcers, stomatitis, aphthous ulcers, and abcesses (*see* Column 4, lines 31-37; Column 8, lines

36-42; Column 9, line 66 to Column 10, line 4; and Column 10, lines 30-51); and, Shuch suggests that compositions comprising herbal ingredients and homeopathics act together to reduce and prevent major chronic diseases of the mouth and can be incorporated into the making of a variety of delivery systems for application to gums and oral mucosa tissue (*see* Column 1, lines 24-53 and Column 8, lines 50-60.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten,* 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi,* 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett,* 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference.

According, the claimed the invention was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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